controlling agent; fenofibrate; an immuno-suppressive peptide; cyclosporine; a protein used in the treatment of diabetes; insulin; and a derivative of insulin.

IN THE CLAIMS:

Replace the indicated claims with:

16. (Twice Amended) A composition comprising stable solid particles of a water-insoluble biologically active substance of a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which said biologically active substance is not soluble or is poorly soluble, and is present in an amount such that the water-insoluble biologically active substance remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition,

wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non-aqueous hydrophobic liquid containing particles of surface stabilized water-insoluble biological substance suspended in the oily droplets of the dispersion and particles of said water-insoluble biologically active substance migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

23. (Twice Amended) The composition of claim 16, wherein the biologically active substance is selected from the group consisting of nifedipine, ursodiol, budesonide, paclitaxel, camptothecin, a derivative of paclitaxel, a derivative of camptothecin, piroxicam, itraconazole, acyclovir, a derivative of acyclovir, fenofibrate, cyclosporine, and insulin.

30. (Amended) A process for preparing a dosage form of a biologically active substance comprising adding to a fluid aqueous medium a composition comprising stable solid particles of said water-insoluble biologically active substance having a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

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a non-aqueous hydrophobic liquid in which said biologically active substance is not soluble or is poorly soluble and is present in an amount such that the water-insoluble biologically active substance remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substance that provides a self-dispersing property to said composition,

wherein upon addition of said composition to said fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non-aqueous hydrophobic liquid containing particles of said surface stabilized water-insoluble biologically active substance suspended in the oily droplets of the dispersion and particles of said water-insoluble biologically active substance migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

36. (Twice Amended) The process of claim 30, wherein the biologically active substance is

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selected from the group consisting of nifedipine, ursodiol, budesonide, paclitaxel, a derivative of paclitaxel, camptothecin, a derivative of camptothecin, piroxicam, itraconazole, acyclovir, a derivative of acyclovir, cyclosporine, and insulin.

Add the following claims:

39. (New) A composition comprising stable solid particles of itraconazole of a volume

C6

weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which itraconazole is not soluble or is poorly soluble, and is present in an amount such that the itraconazole remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition, wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non-aqueous hydrophobic liquid containing particles of surface stabilized itraconazole suspended in the oily droplets of the dispersion and particles of said itraconazole migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

C6 cont.

40. (New) The composition of claim 39, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of less than 25 mg/mL of the non-aqueous hydrophobic liquid.

41. (New) The composition of claim 40, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of from 0.02 to 16.0 mg/mL of the non-aqueous hydrophobic liquid.

42. (New) The composition of claim 39, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyl oleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, ethyl alcohol, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, PEG-200, PEG-300, PEG-400, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

43. (New) The composition of claim 42, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl

myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

44. (New) The composition of claim 43, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, soybean oil, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, apricot kernel oil, linoleic acid, triethyl citrate, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

C1 cont.

45. (New) The composition of claim 39, wherein at least one surfactant component is selected from the group consisting of a natural or synthetic amphiphilic agent; a phospholipid; a nonionic surfactant; a polyoxyethylene fatty alcohol ether; a sorbitan fatty acid ester; a polyoxyethylene sorbitan fatty acid ester; glycerol triacetate; triacetin; a polyethylene glycol; cetyl alcohol; cetostearyl alcohol; stearyl alcohol; a poloxamer; a polaxamine; a polyoxethylene castor oil derivative; vitamin E; D-alpha-tocopheryl polyethylene glycol 1000 succinate; vitamin E TPGS; a PEG glyceryl fatty acid ester; PEG-8 glyceryl caprylate/caprate; PEG-4 glyceryl caprylate/caprate; PEG-32 glyceryl laurate; PEG-6 glyceryl mono oleate; PEG-6 glyceryl linoleate; a propylene glycol mono fatty acid ester; a propylene glycol di-fatty acid ester; propylene glycol laurate; propylene glycol caprylate/caprate; diethylene glycol monoethyl ether; transcutol; a monoglyceride; an acetylated monoglyceride; glycerol monooleate; glycerol monostearate; a mono-acetylated monoglyceride; a di-acetylated monoglyceride; monoacetin; diacetin; an anionic surfactant; a fatty acid salt; a bile salt; potassium laurate; triethanolamine stearate; sodium lauryl sulfate; an alkyl polyoxyethylene sulfate; sodium alginate; dioctyl sodium sulfosuccinate; sodium carboxymethylcellulose; calcium carboxymethylcellulose; a cationic surfactant; a pharmaceutically acceptable quaternary ammonium compound; benzalkonium chloride; cetyltrimethylammonium bromide; lauryldimethylbenzylammonium chloride; polyethylene glycol; PEG 1000; PEG 1500; and PEG 3400.

46. (New) The composition of claim 45, wherein the phospholipid is selected from the group consisting of a saturated phospholipid, an unsaturated phospholipid, a synthetic phospholipid, a natural phospholipid, and a combination thereof.

47. (New) The composition of claim 39, wherein at least one hydrophilic component is selected from the group consisting of a low-molecular weight monohydric alcohol; a low-molecular weight polyhydric alcohol; ethanol; a glycol; glycerol; and a mixture thereof.

48. (New) The composition of claim 39, in a dosage form for peroral, parenteral, transdermal, inhalation, or ophthalmic administration of said biologically active substance.

49. (New) A process for preparing a dosage form of itraconazole comprising adding to a fluid aqueous medium a composition comprising stable solid particles of itraconazole having a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which said itraconazole is not soluble or is poorly soluble, and is present in an amount such that the itraconazole remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition, wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non aqueous hydrophobic liquid containing particles of surface stabilized itraconazole suspended in the oily droplets of the dispersion and particles of said itraconazole migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

50. (New) The process of claim 49, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of less than 25 mg/mL of the non-aqueous hydrophobic liquid.

51. (New) The process of claim 50, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of from 0.02 to 16.0 mg/mL of the non-aqueous hydrophobic liquid.

52. (New) The process of claim 40, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyl oleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, ethyl alcohol, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, PEG-200, PEG-300, PEG-400, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

53. (New) The process of claim 52, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

54. (New) The process of claim 53, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, soybean oil, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, apricot kernel oil, linoleic acid, triethyl citrate, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.